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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,813	01/12/2004	Torben Halkier	0201us622	1688

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,813	HALKIER ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *5 and 14-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of Group I, claims 1-13 in the reply filed on 8/21/2006 is acknowledged. Applicants' further election without traverse of the species on 5/14/2007 is likewise acknowledged. The elected species are as follows: "WHAT IF" computer program from subgroup A, localized mutagenesis from subgroup B, mammalian cell from subgroup C, and polymer molecule from subgroup D.

Claims 5, 6 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/21/2006 and 5/14/2007.

Status of Claims

Claims 1-21 are pending in the application.

Claims 5 and 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species.

Claims 1-4 and 7-13 are under examination.

Oath/Declaration

The oath/declaration is missing i.e., there is no oath on the record

Specification

The specification is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 11, line 12; page 49,line 4. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate description of the computer program that evaluates the primary and tertiary structure of an unnamed or unstructured polypeptide encoded by an unnamed or unstructured polynucleotide. One cannot ascertain from the disclosure as to what is included or precluded by the "WHAT IF" computer program, which appears to be a commercial (trademark) software. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Non-sequitur for the "at least a subset of the diversified population of nucleotide sequences as recited in step 1, c). Step b recites a selected region. The term "altered" or "improved" is a relative term which renders the claim indefinite. Each of these terms is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. These terms are relative terms especially in the absence of any specific recitation of what constitutes a functional polypeptide conjugate.

2. Non-sequitur for "the primary or tertiary structure" in claim 2 or claim 3.

3. Claim 3 contains the trademark/tradename of the computer program name e.g., "WHAT IF". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with

the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a computer program and, accordingly, the identification/description is indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is

shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 7-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of U.S. Patent No. 6933367 ('367 patent)or claim 1, 13 and 23 of U. S. Patent No. 6806063 ('063 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method which recites broadly the claimed method steps of e.g., claim 1 encompasses the method steps of the '367 patent or '063 (see e.g., claim 1) which recites specific substitutions at specific positions of a polypeptide.

Claims 1-4 and 7-13 are provisionally rejected on the ground of nonstatutory double patenting over claim 63 of copending Application No. 11/396,314. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

See the above rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 3-4 and 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Halkier et al (20040014948).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1, 3-4 and 7-13 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Halkier discloses at the following paragraphs:

[0051]…The polypeptide may be a variant (mutant form) of a native or wild-type ligand for a given receptor which furthermore is provided in single-chain form. Modification may be accomplished by suitable deletion, insertion, substitution or addition of one or more amino acid residues within the receptor-binding site (reads on claim 1, steps a and b).

[0052] The total number of amino acid residues.... (as compared to the amino acid sequence of the receptor-binding site of the parent polypeptide) will typically not exceed 15. A receptor-binding site of the single-chain polypeptide thus preferably comprises an amino acid sequence which differs in 1-15 amino acid residues from the amino acid sequence of the corresponding receptor-binding site in the parent polypeptide in question, such as in 1-8 or 2-8 amino acid residues, e.g. in 1-5 or 2-5 amino acid residues (the region, as claimed). Thus, normally the polypeptide comprises an amino acid sequence which differs from the amino acid sequence of the receptor-binding site of the parent polypeptide in 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 amino acid residues, (reads on claim 7).

[0060] …as an alternative to or for further improvement of the above described amino acid residue modification, a receptor-binding site may be blocked by a non-polypeptide moiety. Said non-polypeptide moiety is conjugated or otherwise coupled to the single-chain polypeptide through an attachment group of an amino acid residue which is located so as to allow the conjugated non-polypeptide moiety to block the receptor-binding site. The non-polypeptide moiety may for instance be a ***polymer molecule***, a carbohydrate (or oligosaccharide) molecule, a lipophilic molecule or an organic derivatizing agent. The "polymer molecule" is a molecule formed by covalent linkage of two or more monomers, wherein none of the monomers is an amino acid residue, except where the polymer is human albumin or another abundant plasma protein. The term "polymer" may be used interchangeably with the term "polymer molecule". The term is intended to cover carbohydrate molecules, although,

normally, the term is not intended to cover the type of carbohydrate molecule which is attached to the polypeptide by in vivo N- or O-glycosylation (as further described below). Except where the number of non-polypeptide moieties, e.g. polymer molecules, is expressly indicated, every reference to e.g. a "polymer" or "polymer molecule" contained in a single-chain polypeptide of the invention or otherwise used in the present context shall be understood to be a reference to one or more such polymer molecule(s), (for claim 1, step d and e and claims 8-10).

[0112] The present invention further relates to a method for preparing a single-chain oligomeric polypeptide of the invention, which method comprises culturing a recombinant host cell comprising a single nucleotide sequence encoding said polypeptide in a suitable culture medium under conditions permitting expression of the nucleotide sequence and recovering the resulting polypeptide from the cell culture. In further aspects the invention relates to a nucleotide sequence encoding a single chain oligomeric polypeptide of the invention, an expression vector comprising said nucleotide sequence and a recombinant host cell comprising said sequence or said vector.

Claim 4 is described at paragraph [0456].

Claim 13 is disclosed at paragraph [0501].

Accordingly, Halkier fully meets the broad claimed method.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly

or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2 and 4-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyle et al (7005413).

Boyle discloses at col. 18 line 61 up col. 19, line 24:

> .....One may make many molecules derived in sequence from the molecules in which amino acids have been deleted ("deletion variants"), inserted ("addition variants"), or substituted ("substitution variants"). Molecules having such substitutions, additions, deletions, or any combination thereof are termed individually or collectively "variant(s)"). Such variants should, however, maintain at some level (including a reduced level) the relevant activity of the unmodified or "parent" molecule (e.g., an sTNFR variant possesses the ability to bind TNF). Hereinafter, "parent molecule" refers to an unmodified molecule or a variant molecule lacking the particular variation under discussion; for example, when discussing substitution below, the parent molecule may be a deletion variant.
>
> Variants may be rapidly screened to assess their physical properties. It will be appreciated that such variant(s) will demonstrate similar properties to the unmodified molecule, but not necessarily all of the same properties and not necessarily to the same degree as the corresponding parent molecule.

Boyle discloses at col. 24, line 50 up to col. 26, line 15:

> ....Chemically modified derivatives of the parent molecule(s) in which the protein is linked to a nonproteinaceous moiety (e.g., a polymer) in order to modify properties. These chemically modified parent molecules are referred to herein as "derivatives". Such derivatives may be prepared by one skilled in the art given the disclosures herein. Conjugates

may be prepared using glycosylated, non-glycosylated or de-glycosylated parent molecule(s) and suitable chemical moieties. Typically non-glycosylated parent molecules and water-soluble polymers will be used. Other derivatives encompassed by the invention include post-translational modifications (e.g., N-linked or O-linked carbohydrate chains, processing of N-terminal or C-terminal ends), attachment of chemical moieties to the amino acid backbone, and chemical modifications of N-linked or O-linked carbohydrate chains. (reads on claim 1).

Suitable, clinically acceptable, water-soluble polymers include but are not limited to polyethylene glycol (PEG), polyethylene glycol propionaldehyde, copolymers of ethylene glycol/propylene glycol, monomethoxy-polyethylene glycol, carboxymethylcellulose, dextran, polyvinyl alcohol (PVA), polyvinyl pyrrolidone, poly-1, 3-dioxolane, poly-1,3,6-trioxane, ethylene/maleic anhydride copolymer, poly (.beta.-amino acids) (either homopolymers or random copolymers), poly(n-vinyl pyrrolidone) polypropylene glycol homopolymers (PPG) and other polyalkylene oxides, polypropylene oxide/ethylene oxide copolymers, polyoxyethylated polyols (POG) (e.g., glycerol) and other polyoxyethylated polyols, polyoxyethylated sorbitol, or polyoxyethylated glucose, colonic acids or other carbohydrate polymers, Ficoll or dextran and mixtures thereof. As used herein, polyethylene glycol is meant to encompass any of the forms that have been used to derivatize other proteins, such as mono-(C1-C10) alkoxy- or aryloxy-polyethylene glycol. Polyethylene glycol propionaldehyde may have advantages in manufacturing due to its stability in water.

There are a number of attachment methods available to those skilled in the art, including acylation reactions or alkylation reactions (preferably to generate an amino-terminal chemically modified protein) with a reactive water-soluble molecule. See, for example, EP 0 401 384; Malik et al. (1992), Exp. Hematol., 20:1028-1035; Francis (1992), Focus on Growth Factors, 3(2):4-10, published by Mediscript, Mountain Court, Friern Barnet Lane, London N20 OLD, UK; EP 0 154 316; EP 0 401 384; WO 92/16221; WO 95/34326; WO 95/13312; WO 96/11953; WO 96/19459 and WO 96/19459 and the other publications cited herein that

relate to pegylation, the disclosures of which are hereby incorporated by reference. (Reads on claim 4, 7-10)

Pegylation also may be specifically carried out using water-soluble polymers having at least one reactive hydroxy group (e.g. polyethylene glycol). The water-soluble polymer can be reacted with an activating group, thereby forming an "activated linker" useful in modifying various proteins. The activated linkers can be monofunctional, bifunctional, or multifunctional.

Activating groups which can be used to link the water-soluble polymer to two or more proteins include the following: sulfone, maleimide, sulfhydryl, thiol, triflate, tresylate, azidirine, oxirane and 5-pyridyl. Useful reagents having a reactive sulfone group that can be used in the methods include, without limitation, chlorosulfone, vinylsulfone and divinylsulfone. These PEG derivatives are stable against hydrolysis for extended periods in aqueous environments at pHs of about 11 or less, and can form linkages with molecules to form conjugates which are also hydrolytically stable. Useful
U.S. Pat. No. 4,554,101 also teaches the identification and preparation of epitopes from primary amino acid sequences on the basis of hydrophilicity.

Boyle discloses at col. 23, lines 19-47:

Through the methods disclosed in U.S. Pat. No. 4,554,101 a skilled artisan would be able to identify epitopes, for example, within the amino acid sequence of an sTNFR. These regions are also referred to as "epitopic core regions". Numerous scientific publications have been devoted to the prediction of secondary structure, and to the identification of epitopes, from analyses of amino acid sequences (Chou and Fasman (1974), Biochemistry, 13(2):222-245; Chou and Fasman (1974), Biochemistry, 13(2):211-222; Chou and Fasman (1978), Adv. Enzymol. Relat. Areas Mol. Biol., 47:45-148; Chou and Fasman (1978), Ann. Rev. Biochem., 47:251-276 and Chou and Fasman (1979), Biophys. J., 26:367-384, the disclosures of which are incorporated herein by reference). Moreover, computer programs are currently available to assist with predicting antigenic

> portions and epitopic core regions of proteins. Examples include those programs based upon the Jameson-Wolf analysis (Jameson and Wolf (1988), Comput. Appl. Biosci., 4(1):181-186 and Wolf et al. (1988), Comput. Appl. Biosci., 4(1):187-191, the disclosures of which are incorporated herein by reference); the program PepPlot.RTM. (Brutlag et al. (1990), CABS, 6:237-245 and Weinberger et al. (1985), Science, 228:740-742, the disclosures of which are incorporated herein by reference); and other programs for protein tertiary structure prediction (Fetrow and Bryant (1993), BIOTECHNOLOGY, 11:479-483, the disclosure of which is incorporated herein by reference). (Reads on claims 2 and 3).

Claims 11 and 12 are disclosed at Example 1. See further e.g., Example 1 for a detailed description of the method.

The specific process steps and components used in the process by Boyle fully meet the broad claimed method of no named compound or structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle in view of applicants' disclosure of known prior art.

Boyle is discussed above. Boyle does not disclose a computer program as the elected "WHAT IF as claimed. However, Applicants state at page 50, lines 3-8:

> The model structure can be constructed using any suitable ***software known in the art***, such as, for example, the software Modeller….. the software WHAT IF: A molecular modeling and drug design program (G.Vriend, J. Mol. Graph. (1990) 8, 52-56). (Emphasis added.)

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the computer software(program), WHAT IF in the method of Boyle as taught by the known prior art cited by applicants. It would be within one having ordinary skill in the art to pick and choose any of the commercially available computer programs with a reasonable expectation of successfully obtaining the primary and/or tertiary structure of a given polypeptide. Using a computer software one can easily or readily envision, predict or calculate the tertiary or primary structure of a peptide especially as applied to the modifications being made therein.

Conclusion

Altmann et al (6225446) discloses the MODELLER program.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
August 3, 2007